

### **REMARKS**

This Application has been carefully reviewed in light of the Office Action mailed January 9, 2007. At the time of the Office Action, Claims 1-9, 14, 16 and 20-28 were pending in this Application. Claims 1-9, 14, 16 and 20-28 were rejected. Claims 1, 6-9, 16 and 20-26 have been amended to further define various features of Applicants' invention. Claims 10-13, 15 and 17-19 were previously cancelled due to an election/restriction requirement. Applicants respectfully request reconsideration and favorable action in this case.

#### **Specification Objections**

The abstract for the current application is only 132 words long. Correction is not required. Withdrawal of this objection is requested.

#### **Claim Objections**

Claims 6-9, 16, 21-23, 25, 26 and 28 were objected due to the recitation of certain phrases, which the Examiner recommended be replaced with alternative language.

Applicants have amended claims 6, 21 and 25 as well as claim 24 to further specify that the "guide" in the relevant base claims is a "hollow guide."

Applicants have amended claims 7, 22 and 26 to refer to the "first and second set of projections" in the relevant base claims.

Applicants have amended claim 8 to refer to the "first and second set of projections" in the relevant base claims.

Applicants have deleted the inappropriate "a" in claim 9.

Although Applicants believe it would be clear to one of ordinary skill in the art that the "collection bag" in claims 16 and 23 refers to the "fluid collection bag" in relevant base claims, Applicants have amended these claims to recite the full term, "fluid collection bag."

Applicants have not amended claim 28 as requested. Applicants believe a needle is recited as a positive feature of Claim 1. Applicants have amended claim 1 as well as claims 20 and 23 to make this clearer.

Applicants believe the Examiner's objections have been adequately addressed by these amendments. Withdrawal of the objections is requested.

**Rejections under 35 U.S.C. §103**

Claims 1-9, 14, 20-22 and 27-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,387,086 issued to Jean-Marie Mathias et al. ("*Mathias*"), in view of U.S. Patent No. 4,320,769 issued to Edward C. Eichhorn et al. ("*Eichhorn*"). Applicants respectfully traverse and submit the cited art combinations, even if proper, which Applicants do not concede, does not render the claimed embodiment of the invention obvious.

Claims 16 and 23-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Mathias* in view of *Eichhorn*, as applied to claims 1-9, 14, 20-22 and 27-28 above, and further in view of U.S. Patent No. 5,125,920 issued to Noboru Ishida ("*Ishida*"). Applicants respectfully traverse and submit the cited art combinations, even if proper, which Applicants do not concede, does not render the claimed embodiment of the invention obvious.

In order to establish a *prima facie* case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

There is no motivation to combine Mathias and Eichhorn. Mathias relates to a blood sampling system containing bags and tubes. *See e.g.*, Mathias, Figures 1-5. In contrast, Eichhorn relates to a blood collection device directly connected to a needle without any intervening tubes. *See e.g.*, Eichhorn, Figures 1-12. Further, Eichhorn identifies a particular problem in the prior art. According to Eichhorn, "[c]onventional holders do not allow for the insertion of all diameter sizes of collection tubes. As a result, to fill different sized tubes, a number of venipunctures must be made." *Id.* Col. 1, lines 24-27. To solve this problem, Eichhorn provided "a multiple sampling needle assembly with a holder which will

accommodate a number of different sized diameter fluid collection tubes with different sized closures... ." *Id.* Col. 1, lines 36-39. Thus, Eichhorn clearly contemplated use of its invention only with collection devices attached directly to needles. It did not contemplate its use with bag systems, where the problem of multiple sized collection devices could be solved in a number of other manners, such as the inclusion of multiple collection devices or the piercing of a tube instead of the patient with collection devices attached to multiple needles.

Further, even the combination of Mathias and Eichhorn fails to teach the claimed invention. Mathias discloses projections (Mathias reference numerals 98 and 100 and Figures 4C and D), but it does not disclose two sets of projections and its projections only assist in guiding a vial over a needle, not in maintaining any standby position (Col. 7, lines 20-24).

Eichhorn is cited to remedy at least some of the deficiencies of Mathias. In particular, Eichhorn is cited as disclosing two sets of projections, reference numerals 12 and 102. However, projections labeled as reference numeral 12 are shown only in Figures 1-8. Projections labeled reference numeral 102 are shown only in Figures 10, 11 and 13. No single figure shows both sets of projections in a single device, as would be required for Eichhorn to disclose a single device have both a first and a second set of projections. The reason for this becomes very clear through reference to the specification. Figures 1-7 and 8 show two embodiments of the invention. Eichhorn, Col. 2, lines 40-41 and Col. 3, lines 5-7. Figures 9-13 show a different embodiment of the invention. *Id.* Col. 3, lines 12-14.

As shown particularly in Figures 3, 6 and 8, ribs 12 are essentially in straight lines along the length of the holder. As shown in Figures 10 and 13, ribs 102 are in a spiral configuration. *See also, Id.* Col. 3, lines 25-26. Thus, it appears that ribs 12 and ribs 102 could not even be combined in a single holder because they would not fit.

Eichhorn actually discloses two different embodiments, one with ribs 12 and another having ribs 102. Eichhorn does not disclose a single embodiment having a first and a second set of projections as asserted by the Examiner.

Additionally, the ribs in Eichhorn fail to have a structure operable to recited functions. Eichhorn does not teach that ribs 12 or 102 are able to maintain tubes in a standby position. Instead, the purpose of the ribs are merely to allow the holder 10 or 100 to adapt to different size collection tubes. *Id.* Col. 4, lines 15-16 and line 38. This adaptation occurs while the

tube is in the transfer position. In fact, it seems likely that if one attempted to place any tube in holder 10 or 100 in a standby position, it would be ejected due to flexion of ribs 12 or 102.

Ishida is cited only as disclosing tags and not as remedying any of the above deficiencies of Eichhorn and Mathias.

Accordingly, Applicants assert that there is no motivation to combine Eichhorn and Mathias and, even when combined, the references fail to disclose the claimed invention. Withdrawal of all rejections under §103 is requested.

### CONCLUSION

Applicants have made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of the pending claims.

Applicants believe there are no fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 02-0383 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicants' attorney at 512.322.2580.

Respectfully submitted,  
BAKER BOTTS L.L.P.  
Attorney for Applicants



Michelle M. LeCointe  
Reg. No. 46,861

Date: 4/9/07

SEND CORRESPONDENCE TO:  
BAKER BOTTS L.L.P.  
CUSTOMER NO. **23640**  
512.322.2580  
512.322.8383 (fax)